

**Maryland Board of Pharmacy
Public Board Meeting**

**Agenda
February 19, 2020**

Name	Title	Present	Absent
Ashby, D.	Commissioner		
Bouyoukas, E	Commissioner		
Evans, K.	Commissioner		
Hardesty, J.	Commissioner/Treasurer		
Leikach, N.	Commissioner		
Morgan, K.	Commissioner/President		
Oliver, B	Commissioner		
Rusinko, K.	Commissioner/Secretary		
Singal, S.	Commissioner		
Yankellow, E.	Commissioner		
Bethman, L.	Board Counsel		
Felter, B.	Board Counsel		
Speights-Napata, D.	Executive Director		
Fields, E.	Deputy Director /Operations		
James, D.	Licensing Manager		
Leak, T.	Compliance Director		
Clark, B.	Legislative Liaison		
Chew, C.	Management Associate		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
I. Executive Committee Report(s)	A.) K. Morgan, Board President 		

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			<table><tr><td>Distributor</td><td>13</td><td>2</td><td>0</td><td>1,365</td></tr><tr><td>Pharmacy</td><td>10</td><td>0</td><td>0</td><td>2,045</td></tr><tr><td>Pharmacist</td><td>49</td><td>470</td><td>0</td><td>12,385</td></tr><tr><td>Vaccination</td><td>26</td><td>160</td><td>0</td><td>4,898</td></tr><tr><td>Pharmacy Intern - Graduate</td><td>1</td><td>0</td><td>0</td><td>53</td></tr><tr><td>Pharmacy Intern - Student</td><td>8</td><td>11</td><td>0</td><td>711</td></tr><tr><td>Pharmacy Technician</td><td>122</td><td>348</td><td>5</td><td>9,836</td></tr><tr><td>Pharmacy Technician- Student</td><td>4</td><td>0</td><td>0</td><td>33</td></tr><tr><td>TOTAL</td><td>239</td><td>991</td><td>5</td><td>31,548</td></tr></table>	Distributor	13	2	0	1,365	Pharmacy	10	0	0	2,045	Pharmacist	49	470	0	12,385	Vaccination	26	160	0	4,898	Pharmacy Intern - Graduate	1	0	0	53	Pharmacy Intern - Student	8	11	0	711	Pharmacy Technician	122	348	5	9,836	Pharmacy Technician- Student	4	0	0	33	TOTAL	239	991	5	31,548	
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E. Compliance	T. Leak, Compliance Director	<div>1. Unit Updates</div> <div>2. Monthly Statistics</div> <div>Complaints & Investigations:</div> <div>New Complaints - 38<ul style="list-style-type: none">Customer Service – 3Refusal to Fill – 3Employee Pilferage – 5Professional Misconduct – 4Sterile Compounding issue – 1</div>																																															

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		<ul style="list-style-type: none"> • Hot Water – 1 • Compounding for Office use – 1 • Rx Only – 1 • OCSA Referral – 1 • Not a Repository Site – 1 • Expired CDS Registration – 1 • Expired Medications – 1 • Unsanitary Conditions – 1 • Dispensing Error – 1 • Medication Error – 2 • CPR Cert. (not provided during inspection) – 1 • Disciplinary Action in Another State – 7 • VPP Inspection Issues – 3 <p>Resolved (Including Carryover) – 56 Actions within Goal – 54/56 Final disciplinary actions taken – 23 Summary Actions Taken – 1 Average days to complete – 28</p> <p>Inspections:</p> <p>Total - 161 Annual Inspections - 148 Opening Inspections - 4 Closing Inspections - 3 Relocation/Change of Ownership Inspections - 4 Board Special Investigation Inspections – 2</p>	
F. Legislation & Regulations	B. Clark, Legislative Liaison	<u>Regulations</u>	

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		<u>Legislation</u>	
III. Committee Reports A. Practice Committee	Evans, K. Commissioner	<p>Mohamed Dungarsi: Would it be possible to assist in providing clarity of the following law:</p> <p>Under 12-6c-01(u)(2)(vi), pharmacies are permitted to sell minimal quantities of prescription drugs for office use. Can you confirm if this would require a prescription written for “office use” from the prescriber? Or how would this transaction be documented?</p> <p>Also, if an MD does request CDS for office use, would this method above be appropriate? What additional requirements would apply? I reviewed the board newsletter from summer 2019 but I’m still not clear on this.</p> <p>Proposed response: 1. You may purchase or sell minimal quantity or prescription drugs for office use with an invoice for office.</p> <p>2. Under citation 21 CFR 1306.04(b), which states "A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients."</p> <p>Kristin Denne: Kristin.denne@gmail.com: Walmart & Sam’s Club Pharmacies are in the process of establishing a program whereby all original hard copy prescription records, and other pharmacy records (such as invoices) will be sent to an off-site storage facility for long-term storage. For this project, we are trying to determine how long the original, hard copy records must be maintained in the pharmacy (or other storage site within the retail building) prior to sending to an off-site facility. By reviewing the regulations, I understand how long prescription records must be maintained, however, <u>I am trying to determine the earliest point at which prescriptions can be maintained at a location other than at the pharmacy.</u></p>	

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		<p>With the assumption that all hard copy prescription records will be scanned into our prescription management software and maintained electronically, please assist by answering the following:</p> <p>How long must original hard copy prescriptions be stored on-site at the pharmacy, prior to being sent off-site?</p> <ul style="list-style-type: none"> • Does the Board have to be notified of the name of the facility and the location where the records will be stored long-term? • Are there any other considerations that should be taken into account relative to long term off-site records storage? <p>Proposed response: Yes,</p> <p>Maryland Code Health Occupations Title 12-Pharmacist and Pharmacies, and</p> <p>Subtitle 4-Pharmacy Permits§ 12-403. Required standards (13) Shall:</p> <p>Make and keep on file for at least 5 years a record of each prescription prepared or dispensed in the pharmacy</p> <p>Written notification is not required to the Board.</p> <p>You may check with other regulatory agencies <u>to determine their document retention requirements</u></p> <p>E. LaVerne Braxton-Thomas-Department of Family Services: I am dealing with a case in which a resident, Type II Diabetic, was presented with Humalog Insulin in a nursing home, when his doctor had prescribed for him Novolog. When the resident refused to take it, the nurse told him that the pharmacy does this all the time, and they will switch out one medication for the other routinely.</p> <p>My question is: (1) Does a Pharmacy automatically switch out insulin without a doctor's order? (2) Isn't Humalog generally given to Type 1 Diabetes, although in some cases I am aware that Type II may take it as</p>	

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		<p>well? (3) Isn't Novolog general given to Type II Diabetic only? Please advise me as to the appropriate protocol for something like this.</p> <p>Proposed response: 10.34.10.01C(2) provides as follows:</p> <p>(2) A pharmacist who provides a pharmacy service to a patient of a hospital, as defined in Health-General Article, §19-301, Annotated Code of Maryland, or a resident of a comprehensive care or extended care facility, as defined in COMAR 10.07.02.01B, may perform a therapeutic interchange without the prior approval of the authorized prescriber if the governing body of the hospital, comprehensive care facility, or extended care facility has established procedures for therapeutic interchange.</p> <p>Maren Steensen – Unitypoint: I work at a home infusion pharmacy located in Urbandale, Iowa. I have a patient who receives a weekly shipment of iv fluids, who may be seeking care at Johns Hopkins in the future. The family asked me today if we were able to supply his iv fluids while he was staying in Maryland. Are we able to ship to this patient while he is out of state?</p> <p>Proposed response: In order to dispense a prescription to a patient in Maryland, a Maryland pharmacy permit is required. Alternatively, the prescription may be transferred to a pharmacy located in Maryland.</p> <p><u>Karla is Recused</u></p> <p>Stephanie Oster – Medstar Retail Pharmacies: If a pharmacy technician is working in a remote location, can they perform claim adjudication without a licensed pharmacist present? I think I have inquired about this before but I honestly don't recall where we landed.</p> <p>Proposed response: If adjudication is purely a financial function and does not require clinical judgment or manipulation of prescription information, then it is not considered a delegated pharmacy act no supervision is required.</p> <p>Royce Buruss-Biomatrixsprx: Background: My pharmacy, Biomatrix Specialty Pharmacy of Maryland, LLC, (BMXMD) is now owned by</p>	

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		<p>Biomatrix Specialty Pharmacy (BMXSP). BMXSP owns other specialty pharmacies in various states. The pharmacies have a common computer system from WellSky (CPRPlus® and CareTend®) for specialty pharmacy. The Maryland pharmacy's primary care model consists of: orphan drugs, investigational drugs, oncology, neurology, transplant, and other specialty pharmaceuticals. It does not do sterile or non-sterile compounding and does not dispense controlled drug substances (CDS). It is both URAC and ACHC accredited for specialty pharmacy.</p> <p>Opportunity: There is an opportunity for the branches to operate as "Centers of Excellence" (COE) for selected kinds of specialty pharmacotherapies, e.g., oncology, neurology, transplant, hemophilia, etc. and to help each other process/fill prescriptions more efficiently while offering patients the advantage of having interaction with pharmacists who have subject matter expertise in one or more of the specialties listed. In the course of doing this, these pharmacies may enter prescriptions for a different sister pharmacy to fill as well as do clinical assessments and patient education for patients who have received a prescription dispensed from a sister pharmacy.</p> <p>I'm informing you of my intention as PIC of the MD pharmacy and am requesting feedback regarding this, including inquiring about any pharmacolegal hurdles from a MD BOP perspective.</p> <p>Proposed response: At minimum any out of state pharmacy is required to have a permit in Maryland and a Maryland pharmacist on staff.</p> <p>Please consult with your own counsel with any other legal questions with clinical models.</p> <p>Jermaine Smith – Rite Aid Pharmacy: I was wondering if you could point me in the right direction. The company is considering establishing a mandatory 30 minute lunch/rest period for our pharmacists. In our research we have found that some states would allow registered technicians to remain in the pharmacy to process scripts and allow patients to pick-up re-filled prescriptions.</p> <p>Since establishing registration for technicians and interns would we be allowed to have the registered technicians or interns remain in the pharmacy</p>	

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		<p>or would we be required to close the pharmacy completely during that 30 minute lunch/rest period?</p> <p>Proposed response: If the pharmacist is on break but is immediately available onsite to supervise the delegated pharmacy acts of a technician or intern, the pharmacy can remain open. If the pharmacist is not immediately available on the premises of the pharmacy, the pharmacy area must be closed.</p> <p>Shirish Patel – Chase Brexton Healthcare Pharmacy: Chase Brexton pharmacy currently has four separate locations (Baltimore, Randallstown, Columbia, and Glen Burnie). Each one is independently licensed, with the Baltimore location being our primary location. We also have an offsite clinic in Easton, Maryland, where one of our physician providers sees HIV patients two times a week. From a pharmacy stand point, we were trying to figure out a lawful, expeditious and efficient way to take care of the medication needs for these patients on these two days. The anticipated prescription volume is very low (about 5 prescriptions or so a day). Medications in questions would be HIV related, and non-controlled substance type medications. The goal would be to dispense the first doses/first fill expeditiously with the expectation of servicing refills, if any, via our prescription delivery service from the Baltimore pharmacy location. We currently process a few prescriptions for the Easton location though a messenger delivery service for prescriptions that are faxed to us.</p> <p>Would it be permitted to have one of our pharmacists from the Baltimore location visit the clinic in Easton on these two days, and dispense medications on demand secondary to a physician order? The pharmacist would operate under the auspices of the Baltimore pharmacy location, bill prescriptions to third party carriers using a computer on wheels (COW), label and dispense patient specific medications with standard due diligence. The COW would be stocked with a limited number of medications in secure, locked drawers in the COW. When not in use, we would keep the COW locked and secure in an office area solely under the control of the Chase Brexton Pharmacy Department in Baltimore. Alternatively, the pharmacist could carry this supply of limited medications to and fro from the Baltimore locations of the day of his/her visit to Easton.</p>	

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B. Licensing Committee	D. Ashby, Chair	<p>1. Review of Pharmacist Applications:</p> <p>a. #120462 - The applicant is requesting an extension of her MDBOP application packet and to be granted eligibility to retake the NAPLEX exam for a 6th attempt. The applicant has taken the NAPLEX exam with Maryland twice (failed) and three (failed) attempts with the state of Virginia. She also states that she is planning to take the NAPLEX exam mid-end March. She has not taken the MPJE exam as of yet. <i>Committee's recommendation: Approve</i></p> <p>b. #120206 - The applicant is addressing the Board with another request to be granted for an extension of both his NAPLEX score report (which expired on 12/17/2019) and his MDBOP application packet (which expired on 1/29/2020). The applicant has addressed the Board previously on the December 2019 agenda, to be allowed to retake the MPJE for a 6th attempt and was granted approval at that time. <i>Committee's recommendation: Approve, must reapply</i></p> <p>c. FAS - Requesting the waiver of the required 520 Internship hours'/Pharmacy experience hours for a foreign graduate. The individual does not have official internship hours, however, they have 4 years</p>	

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		<p>of documented full time work as a licensed pharmacist since 2016. (licensed in TX, NE, IA and OK) The individual states that they are FPGE certified since 2010.</p> <p>The Board is awaiting documentation to be emailed by Monday January 27th. (Responded via email on 01/23/2020)</p> <p><i>Committee's recommendation: Approve</i></p> <p>d. #121879 - The applicant is requesting an extension of his MDBOP application, which is due to expire on 06/05/2020. He would also like to inquire if he is eligible for an application fee waiver due to his active duty status. The applicant is currently on active duty orders with the Navy from 10/2019 till 08/2020.</p> <p><i>Committee's recommendation: Approve both for one year.</i></p> <p>e. LEK - The licensee failed to renew their license by the expiration date. Per the Call Center the licensee did not contact the Board until February 3, 2020 @3:29 PM. She is not practicing in the state of Maryland currently, but would like to keep her status active. Per the Boards database system, the licensee has been working for nonresident Hospital since 12/26/2017. She would like the reinstatement application and fee waived.</p> <p><i>Committee's recommendation: Deny</i></p> <p>2. Review of Pharmacy Intern Applications:</p> <p>a. LW - Intern registration expired 01/31/2020, she is requesting an extension of her registration until 05/31/2020. She has already renewed once. She</p>	

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		<p>was initially expected to graduate 05/2019, however, due to an “academic delay” she will not graduate until 05/2020. Committee’s recommendation: Approve, extend to 05/31/2020</p> <p>b. ILF – Registrant’s Pharmacy Intern-Student registration expires 07/31/2020, she is requesting a one-year extension until 07/31/2021, until after she graduates. Committee’s recommendation: Approve, extend to 6/30/2021</p> <p>3. Review of Pharmacy Technician Applications: NONE</p> <p>4. Review of Distributor Applications: NONE</p> <p>5. Review of Pharmacy Applications:</p> <p>a. MediSuite - Pharmacy is requesting an exemption to Md. Code Ann., Health Occ. § 12-313(b) (14 which prohibits a pharmacist from working for a pharmacy wholly or substantially owned by authorized prescriber. A licensed physician owns 50% of the pharmacy. Committee’s recommendation: Deny</p> <p>b. Beaker Pharmacy - Pharmacy is requesting a waiver of the MD licensed pharmacist requirement. The pharmacy will act as the compounder for a physician and will not serve more than 30 MD patients. Committee’s recommendation: Deny</p> <p>6. Review of Pharmacy Technicians Training Programs:</p>	

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		<p>a. Pillbox Institute - Requesting approval for an exam and training program <i>Committee recommendation: Deny, does not meet criteria</i></p> <p>7. Continuing Education Requests:</p> <p>a. WV - American College of Emergency Physicians (ACEP) 2019 Conference (28.5 hours) <i>Committee's recommendation: Deny</i></p> <p>b. PL - Applying Functional Medicine in Clinical Practice (34.5 hours) <i>Committee's recommendation: Deny</i></p> <p>8. New Business:</p> <p>a. NABP Compounding Accreditation FYI: NABP is offering accreditation for compounding pharmacies</p>	
C. Public Relations Committee	E. Yankellow, Chair	Public Relations Committee Update:	
D. Disciplinary	J. Hardesty, Chair	Disciplinary Committee Update	
E. Emergency Preparedness Task Force	N. Leikach, Chair	Emergency Preparedness Task Force Update	
IV. Other Business & FYI	K. Morgan, President		

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V. Adjournment	K. Morgan, President	<p>A. The Public Meeting was adjourned.</p> <p>B. K. Morgan convened a Closed Public Session to conduct a medical review committee evaluation of confidential applications.</p> <p>C. The Closed Public Session was adjourned. Immediately thereafter, K. Morgan convened an Administrative Session for purposes of discussing confidential disciplinary cases.</p> <p>D. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Closed Public Session and the Administrative Session.</p>	
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